IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN *ex rel.* CATHLEEN FORNEY *Plaintiffs* v. MEDTRONIC, INC. *Defendant*.	Civil Action No. 5:15-cv-6264-EGS ORAL ARGUMENT REQUESTED

RELATOR'S OPPOSITION TO MEDTRONIC'S MOTION TO DISMISS

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INTRODUCTION

Medtronic's motion to dismiss rests primarily on the false premise that Medtronic did not engage in any wrongful conduct. Medtronic argues it did not break the law, or did not know it was breaking the law, when it provided the free staffing. Medtronic repeatedly characterizes the free services as "appropriate customer support" and argues that its sophisticated products made such customer support essential. In short, Medtronic simply sets forth its own view of the facts, and constructs a merits defense to the FAC's charges. But this type of merits defense cannot be resolved prematurely before discovery pursuant to a motion to dismiss under Rule 12(b)(6).

Rather, this Court should deny Medtronic's motion to dismiss (or at the very least grant Relator leave to correct any deficiencies identified by the Court), and allow the parties to conduct discovery. At this early procedural stage, Relator, not Medtronic, is entitled to have all inferences drawn in its favor. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555-556 (2007); *Erickson v. Pardus*, 551 U.S. 89, 93 (2007); *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 508, n.1 (2002); *Christopher v. Harbury*, 536 U.S. 403, 406 (2002); *Nietzke v. Williams*, 490 U.S. 319, 327 (1989); *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974); and *Bistrian v. Levi*, 696 F.3d 352, 365 (3rd Cir. 2012). Medtronic will have its opportunity to plead its merit defenses on summary judgment or trial. But urging the Court to make merits finding at this early stage is inviting the Court to commit reversible error.

STATEMENT OF FACTS

On April 3, 2017, Relator filed the FAC, which sets forth one Count sounding under the False Claims Act. In essence, the FAC alleges Medtronic is liable for "causing" providers to file claims that are false under a "false certification" theory of

liability. To support that legal theory, the FAC alleges the following facts: Medtronic paid kickbacks to health care providers in the form of free staffing services in order to induce providers to buy Medtronic cardiac devices, which are reimbursed by Medicare and Medicaid. See, e.g., FAC at ¶ 1 ("In order to increase its sales, Medtronic paid kickbacks to physicians and hospitals. These kickbacks were paid by providing free surgical, device interrogation and other staffing services, which physicians and hospitals used in lieu of having to pay for their own employees . . .. By paying these staffing kickbacks, Medtronic violated the Medicare and Medicaid anti-kickback laws . . .."; FAC at ¶ 19 ("With respect to each and every claim tainted by Medtronic staffing kickbacks, had CMS known that the physicians and hospitals were accepting staffing kickbacks from Medtronic, CMS would not have paid any of the submitted claims."); FAC at ¶ 23 ("Medtronic paid staffing kickbacks in the form of free surgical support, device follow up (interrogation analysis) and other services to an extensive group of physicians and hospitals across the nation. . . . ***Physicians were induced to remain with Medtronic products by these kickbacks, as the free labor benefitted their bottom line***.") (emphasis added); FAC at ¶ 32 ("Had the United States and the Plaintiff States known that Medtronic was paying kickbacks in the form of free surgical staff services, it would not have relied upon the false certifications and made the payments to the Kickback Recipients.)

The FAC alleged that Medicare and Medicaid programs required providers using Medtronic devices to certify via the CMS 1500 Form to the federal programs that they had not accepted any form of prohibited remuneration. *See* FAC at ¶ 20 ("CMS conditioned payment of claims submitted by physicians and hospitals upon compliance

with the anti-kickback and Stark laws"); FAC at ¶ 20 ("CMS Form 1500 requires those seeking payment from the federal government to certify that they have not engaged in any violations of the federal anti-kickback statue. Specifically, CMS Form 1500 includes the following certification: "In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate and complete; … 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law). . . .")

The FAC alleged Medtronic was well aware of the facts that providers had to certify that they had not received any kickbacks, and well aware of the facts that CMS would not reimburse providers for their purchases of Medtronic devices if CMS learned that they had accepted kickbacks from Medtronic. *See* FAC at ¶ 18 ("Medtronic knew that its customers used CMS Form 1500 to submit invoices for payment to the federal health care system."); FAC at ¶ 17 ("Medtronic is well acquainted with the manner in which its customers billed the federal health care programs. Medtronic spent substantial energy and resources briefing and updating its customers on how to bill the federal health care programs, and obtain maximum reimbursement from the federal government. Medtronic offered free assistance on billing devices to its customers."); FAC at ¶ 19 ("CMS conditioned payment of claims submitted by physicians and hospitals upon compliance with the anti-kickback and Stark laws. With respect to each and every claim tainted by Medtronic staffing kickbacks, had CMS known that the physicians and

hospitals were accepting staffing kickbacks from Medtronic, CMS would not have paid any of the submitted claims.")

The FAC alleged Medtronic caused the providers to submit false claims by paying them prohibited kickbacks (in the form of free staffing). FAC at ¶ 25 ("Medtronic caused false claims to be submitted to fiscal intermediaries for payment. Medtronic's customers (cardiologists and hospitals) billed Medicare, Medicaid, and private insurers to obtain payment for the health care provided to the patients receiving Medtronic devices . . .")

The FAC alleged that Medtronic marketed the free staffing kickbacks as a way to induce providers to buy Medtronic devices rather than those of its competitors. *See* FAC at ¶ 16 ("Yet as part of marketing the devices, Medtronic touted its willingness to provide free services . . . . These district plans were required to include provision of free services as marketing tools. This marketing was aimed at physicians, nurse practitioners, practice administrators, and any others who had any impact on purchasing decisions. Medtronic positioned itself as a "partner" who "adds most value through differentiating service and support to all customers."); FAC at ¶ 23 ("Physicians were induced to remain with Medtronic products by these kickbacks, as the free labor benefitted their bottom line.")

The FAC alleged these free staffing services constitute kickbacks because the devices in question are off-the-shelf commodities that are well known to cardiologists. See FAC at ¶ 16. ("None of these devices is new to cardiologists, as all have been approved for marketing by the Federal Food and Drug Administration for at least five years."); FAC at ¶ 23 ("Medtronic induced physicians and others with purchasing power to select Medtronic devices – ***which are off-the-shelf commodities*** – by offering free

services that benefitted physician practices but increased the costs to the federal and state government programs.") (emphasis added).

The FAC also alleged that the free staffing services constitute kickbacks, not legitimate technical assistance, because Medtronic did not limit staffing services to implantation of devices, but instead continued to provide staffing services long after implantation. FAC at ¶ 23 ("Medtronic provided free services long after the implantation of the device.")

The FAC explained Relator learned about Medtronic's fraudulent scheme acquired through her employment as a District Manager for the Cardio and Vascular Group; and that she knew the scheme was a nationwide scheme. *See* FAC at ¶ 5 ("Relator Forney has direct and independent knowledge of Medtronic's staffing kickbacks and HIPAA violations. She acquired this first-hand knowledge of Medtronic's wrongdoing through a career of employment related to cardiac care, including employment with Medtronic"); FAC at ¶ 12 ("Relator Forney served as District Manager for the Cardio and Vascular Group in Eastern Pennsylvania District. At the direction of her management, she directly participated in certain of the events described in this lawsuit. Among other things, she oversaw the scheduling of the staffing services by her subordinates.); FAC ¶ 25 ("Physicians and hospitals receiving staffing kickbacks presented claims for payment to fiscal intermediaries in all fifty states without disclosing the receipt of the staffing kickbacks, and instead falsely certifying that they had complied with the Anti-Kickback laws and regulations."); FAC ¶ 25 ("This same pattern of providing free services prevailed across the nation, with Medtronic providing multiple surgical, interrogation and other staffing kickbacks on a daily basis.")

The FAC provided specific examples of Medtronic's payment of kickbacks in Pennsylvania, where this Court is located, and where Relator worked. The FAC identified the name of the provider, the date the kickback was provided, and the type of service that Medtronic provided as a kickback. FAC ¶ 25. The FAC also alleged frequency, stating that Medtronic provided "multiple surgical, interrogation and other staffing kickbacks on a daily basis." FAC ¶ 25. The FAC alleged Medtronic's frequency of kickback payments did not vary by location but rather "[t]his same pattern of providing free services prevailed across the nation, with Medtronic providing multiple surgical, interrogation and other staffing kickbacks on a daily basis." FAC at ¶ 25.

The FAC alleged that Medtronic's nationwide kickback scheme continues to date. FAC at ¶ 24 ("To date, Medtronic continues to provide kickbacks in the form of free surgical support, post-implant device interrogation and analysis, and other services. Medtronic provides free staff to clinics, where a Medtronic employee will spend 4 to 8 hours conducting interrogations and other services.")

The FAC alleged Medtronic scheduled the free services (*i.e.* the kickbacks themselves) on two calendaring programs (Google Calendar and SalesForce); so those records will "demonstrate Medtronic's nationwide and continuous payment of surgical staffing kickbacks." *See* FAC, ¶ 26.

The FAC alleged that Medtronic knowingly violated HIPAA by using Google Calendar, and evidence of such knowledge can be discerned from reviewing Medtronic's 10-K for 2013. *See* FAC ¶ 27.

On April 24, 2017, Medtronic filed a Motion To Dismiss the FAC, and a Memorandum of Law in support of its Motion To Dismiss With Prejudice (hereinafter

"Medtronic's Memorandum"). Medtronic argues that this Court should dismiss the FAC with prejudice because it (1) fails to allege a violation of the Anti-Kickback Statute (page 4); (2) fails to alleged Medtronic offered remuneration to induce purchase of its products (pages 5-9); (3) fails to allege Medtronic acted knowingly and willfully (pages 9-11); (4) fails to provide specificity (pages 11-14); (5) fails to connect the kickbacks to the false claims (pages 14-15); (6) fails to allege a Stark violation (pages 15-17); (7) "abandons" HIPAA violation liability (page 17); and (8) fails to allege misconduct outside Pennsylvania (pages 17-18).

In support of its arguments, Medtronic cites to thirteen of the FAC's twenty-eight factual averments; it fails to cite in any way to fifteen of the FAC's twenty-eight factual averments.

ARGUMENT

Relator properly plead a False Claims Act count in the First Amended Complaint (hereinafter "FAC"). The FAC alleges Medtronic, acting on a nationwide basis, paid kickbacks to physicians and hospitals in the form of free staff. *See, inter alia*, FAC at ¶¶ 1, 16, 19, 23, 25, 32. The free staff provided by Medtronic gave the physicians and hospitals a direct financial benefit, as it lessened their own labor costs, and eliminated their need to hire more staff. *See, inter alia* FAC at ¶¶ 16, 23. As explained below in the Argument, Medtronic's provision of free staff qualifies as "in kind" kickbacks that caused providers to buy Medtronic devices, and submit false claims by certifying (via the CMS 1500 form) to the federal programs (Medicare and Medicaid). Medtronic's conduct in paying "in kind" kickbacks via free staffing does not fit into any safe harbor under the Anti-Kickback Statute, and indeed constitutes the type of misconduct specifically

mentioned by the Office of the Inspector General of Health and Human Services in fraud alerts.

Seeking a dismissal with prejudice before any discovery has occurred, Medtronic argues that it is entitled to provide free staff to providers without violating the Anti-Kickback Statute because its devices are complicated and require technical support. *Compare* FAC at ¶ 23 (devices are "off-the-shelf commodities"). But as explained below in Section I, this self-serving claim that Medtronic did not pay kickbacks in the form of free staff lacks any legal support. Contrary to Medtronic's unsupported argument that the kickbacks must be cash payments, the Anti-Kickback Statute clearly captures "in kind" as a form of unlawful remuneration. The caselaw, the statutory and regulatory authorities, as well as even industry codes of conduct, support the FAC allegations: providing free staff confers a financial benefit and constitutes a prohibited "in kind" kickback.

This Opposition also addresses the remainder of Medtronic's various arguments about pleading deficiencies in the FAC. Section II explains how the FAC properly alleged Medtronic acted with the intent in violating the Anti-Kickback Statute when it induced purchase of its products through paying kickbacks in the form of free staff. *See, inter alia*, FAC at ¶¶ 17-20. Section III describes how the FAC satisfies Rule 9(b) and satisfies the pleading jurisprudence on "caused to be made" claims because it pleads with specificity and identifies how two calendaring systems (Google and SaleForce) are able to identify when, where, how and to whom Medtronic provided the free staffing services. *See, inter alia*, FAC at ¶¶ 24-27. Section IV rebuts Medtronic's claim that its devices do not constitute "durable medical equipment" under the Stark law. Section V rebuts

Medtronic's characterization of Medtronic's HIPAA violations as irrelevant. Section VI describes how the FAC, based on Relator's first-hand knowledge gained as an employee of Medtronic, alleges an ongoing nationwide scheme to defraud, not one limited to Pennsylvania. *See, inter alia*, FAC at ¶¶ 24-27.

Finally, Section VII explains that Medtronic fails to provide the Court any reason to dismiss with prejudice even if the Court were to find deficiencies in the FAC. At this early procedural stage, Fed.R.Civ.P. 15(a) and controlling jurisprudence compel the Court to allow the Relator an opportunity to amend the complaint in the event that the Court identifies any pleading deficiencies. Relator believes the FAC satisfies the Federal Rules of Civil Procedure, including Rule 9(b), but stands ready to allege additional facts if deemed necessary by the Court.

I. THE FAC PROPERLY PLEAD MEDTRONIC PAID ILLEGAL KICKBACKS IN THE FORM OF FREE STAFFING AND CAUSED THE FILING OF FALSE CLAIMS.

Medtronic's Memorandum argues that the FAC fails to state a claim. Fed.R.Civ.P. 12(b)(6). At this stage in the proceedings, this Court accepts the Relator's allegations as truth, and draws all possible inferences in Relator's favor. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555-556 (2007); *Erickson v. Pardus*, 551 U.S. 89, 93 (2007); *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 508, n.1 (2002); *Christopher v. Harbury*, 536 U.S. 403, 406 (2002); *Nietzke v. Williams*, 490 U.S. 319, 327 (1989); *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974); and *Bistrian v. Levi*, 696 F.3d 352, 365 (3rd Cir. 2012). Subsection A sets out the applicable legal standard under the False Claims Act and the Anti-Kickback Statute. Next, Subsection B summarizes the FAC allegations, and rebuts

Medtronic's argument (made in various iterations) that those FAC allegations fail to allege wrongful conduct by Medtronic.

A. The Applicable Legal Standard

1. The False Claims Act

To establish a *prima facie* claim under the False Claims Act (FCA), 31 U.S.C. § 3729(a)(1), a plaintiff must show that: "(1) the defendant . . . caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004). "In order to prove a claim under § 3729(a)(2), a plaintiff must also show that the defendant made or used (or caused someone else to make or use) a false record in order to cause the false claim to be actually paid or approved." *Id.*

A company such as Medtronic may be held to have caused the submission of false claims if it provided illegal benefits (*i.e.* kickbacks) to a healthcare provider, knowing that the healthcare provider will seek reimbursement for medical services from federal healthcare programs and knowing that the provider is required by law to certify that it complies with the anti-kickback laws. *See, e.g.*, *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3rd Cir. 2004) ("Schmidt, like the plaintiffs in *Hess* and *Bornstein*, alleges that Zimmer created and pursued a marketing scheme that it knew would, if successful, result in the submission by Mercy and others similarly situated of compliance certifications required by Medicare that Zimmer knew would be false. If this conduct and this knowledge were proven at trial, a jury could conclude that Zimmer knowingly caused Mercy's false claims to be filed."); *U.S. ex rel. Willkins v. United Health Group, Inc.*, 659

F.3d 295, 314. (3rd Cir. 2011); *U.S. ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 665 (W.D. Pa. 2014) ("Falsely certifying compliance with either statute constitutes a "false claim" submitted to the federal government for purposes of the FCA."); *U.S. ex rel. Witkin v. Medtronic, Inc.*, 189 F. Supp.3d 259 (D. Mass. 2016) (denying Medtronic's motion to dismiss because complaint alleged Medtronic knowingly caused providers to submit false claims by providing free services in diabetes clinics). *See also U.S. ex rel. Hopper v. Anton,* 91 F.3d 1261, 1266 (9th Cir.1996) ("[A] false *certification* of compliance [with applicable law] creates liability [under the FCA] when certification is a prerequisite to obtaining a government benefit."); *Harrison v. Westinghouse Savannah River Co.,* 176 F.3d 776, 787 (4th Cir.1999) (stating a certificate of compliance with federal healthcare law, including anti-kickback laws, is a prerequisite to eligibility under the Medicare laws.)

And controlling jurisprudence on the "caused" prong of the False Claims Act teaches us to look to whether the defendant would have known "at least of the claims submitted by a third-party would be kickbacktainted." *U.S. ex. rel Schmidt v. Zimmer*, 386 F. 3rd 235, 243-244; *see also U.S. ex rel. Bergman v. Abbot Laboratories*, 995 F. Supp. 2d 357, 374 (E.D. Pa. 2014).

2. The Anti-Kickback Statute

Thus, to plead a "false certification" claim under the federal False Claims Act, the relator needs to allege facts showing defendant violated the federal Anti-Kickback Statute. That statute is a criminal statute that prohibits offering anything of value in an effort to induce or reward any business that is compensated by federal government's health care programs.

See 42 U.S.C. § 1320a-7b, stating in relevant part:

(b) Illegal remunerations (2) Whoever knowingly and willfully offers or ***pays any remuneration*** (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or ***in kind*** to any person to induce such person— **(B)** ***to purchase***, lease, order, or arrange for or recommend purchasing, leasing, or ordering ***any good***, facility, service, or item ***for which payment may be made in whole or in part under a Federal health care program***, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

Id. (emphasis added.) The Anti-Kickback Statute is broadly drafted and establishes penalties for individuals and entities on both sides of the prohibited transaction.

In *United States v. Greber*, the landmark case regarding the scope of the Anti-Kickback Statute in the context of the False Claims Act, the U.S. Court of Appeals for the Third Circuit established the "one purpose" test. Under the "one purpose" test, "if one purpose of the payment was to induce future referrals, the Medicare statute has been violated." *U.S. v. Greber*, 760 F.2d 68, 69 (3rd Cir. 1985), *cert. denied*, 474 U.S. 988 (1985). This test has also been adopted by the Fifth, Ninth, and Tenth Circuits. See *U.S. v. Davis*, 132 F.3d 1092 (5th Cir. 1998); *U.S. v. Kats*, 871 F.2d 105 (9th Cir. 1989); and *U.S. v. McClatchey*, 217 F.3d 823 (10th Cir. 2000) (*reaff'd., U.S. v. LaHue*, 261 F.3d 993 (10th Cir. 2001)).

Not all transactions caught by the literal terms of the Anti-Kickback Statute are penalized In recognition of its breadth, the Anti-Kickback Statute contains ten very broad categories of conduct that are excluded from consideration by statute. 42 U.S.C. § 1320a-7b(b)(3). In addition to the statutory exclusions from the scope of the Anti-Kickback Statute, the U.S. Department of Health & Human Services ("HHS") Office of Inspector General ("OIG") has been given authority to adopt "safe harbors" to exclude from the definition of "remuneration" certain business practices that are viewed as safe and

unlikely to cause the federal government health care programs to pay more than necessary for products and services. The OIG considers whether the business practices minimize the risk for potential corruption, and issues regulations setting forth safe harbors. *See* 42 C.F.R. § 1001.952.

In addition to both the statutory and regulatory exclusions for non-corrupting conduct, the HHS OIG also has a mechanism in place to allow businesses working in the health care field to ensure that their business conduct does not violate the Anti-Kickback Statute. Companies are permitted to seek an advisory opinion from the OIG that tells them whether or not the planned or ongoing conduct constitutes a prohibited kickback. As explained by the HHS OIG website (oig.hhs.gov>Compliance), "[i]n accordance with 1128(D) of the Social Security Act (42 U.S.C. 1320a-7d(b) and 42 C.F.R. part 1008, OIG issues advisory opinions about the application of OIG's fraud and abuse authorities to the requesting party's existing or proposed business arrangement . . . One purpose of the advisory opinion process is to provide meaningful advise on the application of the anti-kickback statute and other OIG sanction statutes in specific factual situations." *See also* Office of Public Affairs, Office of Inspector General Department of Health & Human Services, Fact Sheet November 1999, Federal Anti-Kickback Laws and Regulatory Safeharbors.

But free staffing such as that provided by Medtronic does not fall into any of these many exclusions from liability. Instead, free staffing on comparable facts has consistently been held to constitute a prohibited "in kind" form of remuneration. Indeed, Medtronic itself has confronted similar allegations regarding its diabetes products. *See U.S. ex rel. Witkin v. Medtronic, Inc.*, 189 F. Supp.3d 259 (D. Mass. 2016). In that case,

Medtronic was accused of providing free services to physicians' offices, namely clinics where a Medtronic representative scheduled sessions for diabetes patients in their doctor's office to be fitted with a Medtronic-manufactured device. Medtronic provided the service of fitting patients with the device and the evaluation of insulin levels for free, often with no physician oversight. *Id.* at *4-5. Medtronic employees would then instruct the physician's office on how to bill federal healthcare programs for the services that Medtronic performed for free. *Id.* at *5.

When Medtronic sought dismissal based on arguments similar to those made here, the District Court denied the motion to dismiss, concluding that, if true, Medtronic's practice of providing free services in the form of patient clinics was an illegal kickback scheme designed to induce doctors to recommend Medtronic products. *Id.* The District Court found that the physician "has received remuneration when he otherwise would have had to expend additional money or time to administer the services himself or pay staff to do so." *Id.* (emphasis original). That is, the provision of staff that perform tasks that a practice would otherwise have to hire additional employees to perform is a kickback. *Id.*

Similarly, in *Ameritox, Ltd. v. Millennium Labs., Inc.*, 20 F. Supp. 3d 1348, 1352–53 (M.D. Fla. 2014), the district court held that a laboratory provided an illegal kickback to physicians by providing urine sample cups that contained paper test strips, which provided immediate preliminary test results in advance of the sample being analyzed at the lab.. The court held that providing test strips was a prohibited kickback because it provided valuable preliminary test results that the physician would otherwise have had to

pay for. *Id.* The court determined the provision of free paper test strips was a free service provided to induce referrals to the lab. *Id.* at 1355-56.

Medtronic has long known the risks it was running in giving providers free staff as "in kind" kickbacks. As early as 1994, the Department of Health and Human Services (DHHS), Office of the Inspector General (OIG), had published a "Special Fraud Alert" identifying as a potential illegal kickback the "[p]rovision of free or significantly discounted billing, nursing or other staff services." Fed. Reg. December 19, 1994.[1] By 1999, the OIG had published a compliance guidance that gave as an example of a kickback a medical device manufacturer providing "services for free or below fair market value to providers…." 64 Fed. Reg. 128 (July 6, 1999).[2] S*ee also* Congressional Testimony of Gregory E. Demske, Assistant Inspector General for Legal Affairs, "*Examining the Relationship Between the Medical Device Industry and Physicians*" (Feb. 27, 2008).[3]

Indeed, even Adva-Med, an industry-controlled trade association, cautioned Medtronic and other device manufacturers against paying such kickbacks: "For example, a Company should not provide free services that would eliminate an overhead or other expense that a Health Care Professional would otherwise of business prudence or necessity have incurred as part of its business operations. . . . " See Revised and Restated Code of Ethics, effective July 1, 2009, at Paragraph X. FAC ¶22**.**

[1] https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html
[2] https://oig.hhs.gov/authorities/docs/frdme.pdf
[3] Available at http://highline.huffingtonpost.com/miracleindustry/americas-most-admired-lawbreaker/assets/documents/8/demske_testimony_financial_ties.pdf

B. The FAC Alleges Facts Sufficient To Prove Medtronic Engaged in Wrongful Conduct.

Medtronic's Memorandum is telling in what it fails to argue. Namely, Medtronic, a sophisticated entity operating in the health care field, fails to argue that its has any legal authority to support its claim that the Anti-Kickback Statute does not reach its misconduct in providing free staff to providers. Medtronic has not – and cannot – claim that its misconduct falls into any of the statutory safe harbors. Nor can Medtronic claims that its misconduct falls into one of the codified "safe harbors" for business practices that do not risk corrupting the federal health care programs. Finally, it appears from Medtronic's Memorandum that Medtronic never sought and obtained an OIG advisory opinion allowing it to provide free staff to providers. Presumably, if Medtronic had done so, the company would have so advised the Court, and appended the OIG advisory opinion.[4]

Instead of offering a legally-sound reason to dismiss the FAC, Medtronic makes two arguments, neither of which persuade. ***First***, Medtronic concocts an argument based entirely on a circular and legally-deficient premise that all of the FAC allegations about free staffing should be ignored because Medtronic's conduct in providing that free staffing constitutes "unexceptional product support" of a lawful nature that does not violate the Anti-Kickback Statute. *See* Medtronic's Memorandum in Support of its Motion to dismiss at 9 ("nor does she allege that the services provided by Medtronic employees exceeded the unexceptional product support discussed throughout the Complaint"); at 7 ("Given these requirements and product technicalities, of course

[4] Discovery will reveal whether Medtronic contemplated seeking an advisory opinion but decided not to do so. Such evidence would further assist the jury in deliberating on the knowing and intentional nature of Medtronic's misconduct.

physicians sought input and technical support from Medtronic representatives before, during, and after implantation"); and at 8 ("Providing product support to a customer who has purchased a computer is expected, and the only difference between that scenario and the one Relator has alleged is that the computer here is implanted in the human body and connected to the heart.").

In making this argument, Medtronic simply ignores the factual allegations in the FAC that allege the opposite. *See, e.g.*, FAC at ¶ 23 (devices are "off-the-shelf commodities"); FAC at ¶ 16 ("[n]one of these devices is new to cardiologists, as all have been approved for marketing by the Federal Food and Drug Administration for at least five years"); FAC at ¶ 23 ("Medtronic provided free services long after the implantation of the device.")

And even absent those FAC allegations, the argument would collapse. Computer companies do not sell products reimbursed by the federal health care programs, and are not subject to the Anti-Kickback Statute, which is designed to prevent corruption of those federal programs. Medtronic is subject to the Anti-Kickback Statute. Medtronic is well aware of the fact that the federal government health care programs pay for the cardiac devices that Medtronic sells to physicians and hospitals. Medtronic's suggestion that the Court ignore the text of the Anti-Kickback Statute and simply reason by analogy to a non-health care context is troubling, and should not persuade. If Medtronic believed it had a legitimate reason to provide extensive free services – including services provided well after the initial device implantation -- it could have gone to the OIG for an advisory opinion granting it permission.

Second, Medtronic's Memorandum argues that the free staffing services cannot be considered prohibited kickbacks because "[t]here are no alleged cash payments made in restaurants, parking lots, or public restrooms. . . There are also no allegations of invoices itemizing the specific referrals for which payments had been made. . . . Nor are there allegations that sales representatives offered payments to physicians as "additional income" in exchange for sales leads." *Medtronic Memorandum* at 11. This argument is mere sophistry, as the Anti-Kickback Statute is not limited in any way to these particular categories. Rather, the Anti-Kickback Statute prohibits ***any*** form of remuneration – whether cash or in kind, whether direct or indirect -- that potentially corrupts the federal health care programs.

The FAC, based on Relator's knowledge gained during her employment with Medtronic, clearly alleges that Medtronic paid prohibited kickbacks in the form of free staff. *See, e.g.*, FAC at ¶ 1 ("In order to increase its sales, Medtronic paid kickbacks to physicians and hospitals. These kickbacks were paid by providing free surgical, device interrogation and other staffing services, which physicians and hospitals used in lieu of having to pay for their own employees . . .. By paying these staffing kickbacks, Medtronic violated the Medicare and Medicaid anti-kickback laws . . .."; and FAC at ¶ 23 ("Medtronic paid staffing kickbacks in the form of free surgical support, device follow up (interrogation analysis) and other services to an extensive group of physicians and hospitals across the nation. . . . Physicians were induced to remain with Medtronic products by these kickbacks, as the free labor benefitted their bottom line.").

The FAC clearly alleges that the providers receiving the kickbacks from Medtronic filed false claims, as they certified on the CMS Form 1500 that their claims

were not tainted by prohibited kickbacks from Medtronic. *See* FAC at ¶ 18 ("Medtronic knew that its customers used CMS Form 1500 to submit invoices for payment to the federal health care system."); FAC at ¶ 17 ("Medtronic is well acquainted with the manner in which its customers billed the federal health care programs. Medtronic spent substantial energy and resources briefing and updating its customers on how to bill the federal health care programs, and obtain maximum reimbursement from the federal government. Medtronic offered free assistance on billing devices to its customers."); FAC at ¶ 19 ("CMS conditioned payment of claims submitted by physicians and hospitals upon compliance with the anti-kickback and Stark laws. With respect to each and every claim tainted by Medtronic staffing kickbacks, had CMS known that the physicians and hospitals were accepting staffing kickbacks from Medtronic, CMS would not have paid any of the submitted claims."); and FAC at ¶ 32 ("Had the United States and the Plaintiff States known that Medtronic was paying kickbacks in the form of free surgical staff services, it would not have relied upon the false certifications and made the payments to the Kickback Recipients.)

The FAC alleges Medtronic paid physicians and others with purchasing power "in kind" kickbacks by giving them free staff that saved them money and on occasion eliminated their need to hire more staff. *See, e.g.*, FAC at ¶ 23 ("Medtronic induced physicians and others with purchasing power to select Medtronic devices – which are off-the-shelf commodities – by offering free services that benefitted physician practices but increased the costs to the federal and state government programs.") In sum, it is clear the FAC alleges all the necessary facts to support a finding that Medtronic wrongfully paid kickbacks in the form of free staffing.

C. Medtronic's Memorandum Resorts to Inaccurate Characterizations of the Text of the FAC.

All of these allegations, taken together, clearly state a cognizable legal claim against Medtronic. Medtronic, lacking any compelling defense, resorts to mischaracterizing the text of the FAC. It makes a series of blanket statements that simply cannot be squared with the text of the FAC. A few examples suffice:

First, Medtronic's Memorandum at 5 argues to the Court "[t[hese allegations do not allege that remunerations was offered or provided to surgeons." But the FAC at ¶ 23 alleges that Medtronic paid kickbacks to "physicians and others with purchasing power": "Medtronic induced physicians and others with purchasing power to select Medtronic devices – which are off-the-shelf commodities – by offering free services that benefitted physician practices but increased the costs to the federal and state government programs."

Second, Medtronic Memorandum at 7 argues that "Relator again fails to plead any facts that Medtronic provided value independent of its products to the surgeon when providing this appropriate customer support." But the FAC alleges that Medtronic paid kickbacks that went well beyond "appropriate customer support": *see* FAC ¶ 1, alleging "[t]hese kickbacks were paid by providing free surgical, device follow up (interrogation analysis), and other staffing services, which physicians and hospitals used in lieu of having to pay for their own employees" and FAC at ¶ 23, alleging "Medtronic paid staffing kickbacks in the form of free surgical support, device follow up (interrogation analysis) and other services to an extensive group of physicians and hospitals across the nation. . . . Physicians were induced to remain with Medtronic products by these kickbacks, as the free labor benefitted their bottom line."

Third, Medtronic Memorandum at 9 represents as fact to the Court that, "[a]s a threshold matter, Relator does not allege that Medtronic employees actually provided clinical staff to customers, let alone that Medtronic provided clinical staff for free that doctors or hospitals would otherwise have had to hire." But the FAC alleges that Medtronic provided clinical staff for free that doctors or hospitals would otherwise have had to hire. Specifically, FAC at ¶ 24 states, "[t]o date, Medtronic continues to provide kickbacks in the form of free surgical support, post-implant device interrogation and analysis, and other services. Medtronic provides free staff to clinics, where a Medtronic employee will spend 4 to 8 hours conducting interrogations and other services;" FAC at ¶ 1 states "[t]hese kickbacks were paid by providing free surgical, device follow up (interrogation analysis), and other staffing services, which physicians and hospitals used in lieu of having to pay for their own employees;" and FAC at ¶ 23 states "Physicians were induced to remain with Medtronic products by these kickbacks, as the free labor benefitted their bottom line."

In short, Medtronic's Memorandum's factual representations about the content of the FAC are not accurate. The FAC speaks for itself, and contradicts many of the blanket statements made in the Memorandum. And ***all*** factual allegations need to be read and considered together, not merely the subset of allegations (13 of the 28 paragraphs) that Medtronic opted to discuss. Medtronic's arguments fail when compared to the actual content of the FAC. As explained above, providing free staff clearly constitutes a kickback, and thus the FAC alleges facts to establish all of the necessary elements of a false certification claim. *See, e.g., U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3rd Cir. 2004); *U.S. ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 665 (W.D. Pa.

2014); *U.S. ex rel. Witkin v. Medtronic, Inc.*, 189 F. Supp.3d 259 (D. Mass. 2016); and *Ameritox, Ltd. v. Millennium Lab., Inc.*, 20 F. Supp. 3d 1348, 1352–53 (M.D. Fla. 2014).

II. *THE FAC ALLEGES MEDTRONIC ACTED WITH THE REQUISITE INTENT.*

Medtronic argues Relator failed to allege facts that create any indicia that Medtronic knew that its conduct was unlawful. "There are no indicia, reliable or otherwise, that Medtronic would have understood itself thereby to be committing a federal crime." *See* Medtronic Memorandum at 11. Medtronic again fails to persuade because it ignores both the legal standard for knowledge, and the factual allegations in the FAC.

A. Applicable Legal Standard

"In the context of the FCA, "the terms 'knowing' and 'knowingly' mean that a person, with respect to information—(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information . . .." *U.S. ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 674 (W.D. Pa. 2014).

The controlling jurisprudence makes clear that Medtronic's payments in kind to the providers constitute prohibited kickbacks if "one purpose" of the payments was to induce providers to buy Medtronic devices. *See* 42 U.S.C. § 1320a-7b. *See U.S. v. Greber*, 760 F.2d 68, 72 (3d Cir.1985) ("If the payments were intended to induce the physician to use Cardio–Med's services, the statute was violated, even if the payments were also intended to compensate for professional services."); *U.S. ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 676 (W.D. Pa. 2014) ("The statute has been broadly

interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for the referral of services or to induce future referrals.")

B. The FAC Alleges Medtronic's Knowledge.

Measuring the text of the FAC against this controlling legal standard proves that the FAC clears the bar. Relator alleged Medtronic acted knowingly and intentionally by marketing the free staffing kickbacks as a way to induce providers to buy Medtronic devices rather than those of its competitors. *See* FAC at ¶ 16 ("Yet as part of marketing the devices, Medtronic touted its willingness to provide free services . . . . These district plans were required to include provision of free services as marketing tools. This marketing was aimed at physicians, nurse practitioners, practice administrators, and any others who had any impact on purchasing decisions. Medtronic positioned itself as a "partner" who "adds most value through differentiating service and support to all customers.")

The FAC alleges Medtronic was knowledgeable about the providers being required to certify that they had not accepted any remuneration from Medtronic. *See* FAC at ¶ 17 ("Medtronic is well acquainted with the manner in which its customers billed the federal health care programs. Medtronic spent substantial energy and resources briefing and updating its customers on how to bill the federal health care programs, and obtain maximum reimbursement from the federal government. Medtronic offered free assistance on billing devices to its customers"), FAC at ¶ 18 ("Medtronic knew that its customers used CMS Form 1500 to submit invoices for payment to the federal health care system."); FAC at ¶ 19 ("CMS conditioned payment of claims submitted by physicians and hospitals upon compliance with the anti-kickback and Stark laws"); FAC at ¶ 20

("CMS Form 1500 requires those seeking payment from the federal government to certify that they have not engaged in any violations of the federal anti-kickback statute . . .")

The FAC alleges Medtronic's intentional payments of kickbacks worked, as physicians bought Medtronic products rather than competing products. *See* FAC at ¶ 23 ("Physicians were induced to remain with Medtronic products by these kickbacks, as the free labor benefitted their bottom line.")

Such allegations suffice to clear the bar on knowledge and intent. *See, e.g., U. S. ex rel. Witkin v. Medtronic*, 189 F.Supp. 259, 270 (D.Mass. 2016)("t]he allegation that Medtronic effectively instructed physicians on billing Medicare for procedures that Medtronic provided for free transforms what would be an otherwise innocuous patient-promotion practice into an offer of remuneration to the physicians.") *See* 42 U.S.C. § 1320a-7b(a). Medtronic intentionally and knowingly marketed its free services in order to influence physicians and others with purchasing power to buy more Medtronic products. Medtronic's kickbacks impose significantly costs and distortions on the Medicare system. And compliance with the Anti-Kickback Statute is clearly a condition of payment under Medicare. *United States ex rel. Willkins v. United Health Group, Inc.*, 659 F.3d 295, 314. (3rd Cir. 2011).

III. THE FIRST AMENDED COMPLAINT SATISFIES RULE 9(b).

Medtronic Memorandum makes two additional arguments for dismissal Medtronic's argument that the Relator failed to satisfy Fed.R.Civ.P. 9(b) ignores controlling Third Circuit jurisprudence. Medtronic argues that the FAC lacks specificity. *See* Medtronic Memorandum at 11-14. And Medtronic also argues that the Relator failed to "pair" the

kickbacks to actual false claims filed by the providers. *See* Medtronic Memorandum at 14-15. But Medtronic errs, both as a matter of law and as a matter of fact.

First, as a matter of law, as explained in Subsection A, this Circuit has rejected an overly rigid standard for False Claims Act cases. *Foglia v. Renal Ventures Management, LLC*, 754 F.3d 153, 156 (3rd Cir. 2014); *Rolo v. City Investing Co. Liquidating Trust*, 155 F.3d 644, 658 (3rd Cir. 1998). And the False Claims jurisprudence on "causing to be made" claims makes clear that Relators do not need to identify the dates when the third-party providers submitted the false certifications. *See US ex rel. Bergman v. Abbot Laboratories*, 995 F. Supp. 2d 357, 374 (E.D. Pa. 2014), citing *John Underwood v. Genetech*, 720 F.Supp. 2d 671, 678 (E.D. 2010). Second, as a matter of fact, as explained in Subsection B, the FAC alleges a nationwide scheme with the fraud occurring daily, which scheme is memorialized in Medtronic's Google and SalesForce calendar programs scheduling the free services. *See* FAC, ¶ 26. In addition, although not necessary under the caselaw, the FAC provides examples of the precise dates and locations when Medtronic delivered the free staffing kickbacks, and identifies the physicians who accepted the kickbacks. *See* FAC, ¶ 25. The FAC clearly survives Medtronic's challenge under Rule 9(b).

A. Applicable Legal Standard

In *Foglia v. Renal Ventures Management, LLC*, 754 F.3d 153, 156 (3rd Cir. 2014), the Third Circuit rejected the rigid standard being urged by Medtronic, and instead held that a Relator does ***not*** need to plead representative samples of the alleged fraudulent conduct, specifying the time, places, and content of the acts and the identity of the actors. That approach – adopted by other circuits – was found to conflict with the terms of the False Claims Act itself, which does "not required that the exact content of the false

claims in question be shown." The Third Circuit also found compelling the position of the United States, which explained in Supreme Court briefing that "pleading the details of a specific false claim presented to the government is not an indispensable requirement of a viable FCA complaint." Indeed, the Solicitor General noted that the rigid standard adopted by other circuits served as an impediment and "undermines the FCA's effectiveness as a tool to combat fraud against the United States. *Id*. at 156.

The Third Circuit instead set forth the pleading standard for FCA complaints: "it is sufficient for a plaintiff to allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." Id. at 156 (internal quotations and citations omitted). As the Third Circuit taught in *Foglia*, 754 F.3d 153, 158 (3rd Cir. 2014), a defendant cannot move for dismissal based merely on a challenge to the Relator's hypothesis: "Although we recognize that this hypothesis could be challenged, it certainly suffices to give Rental notice of the charges against it, as is required by Rule 9(b)."

See also Rolo v. City Investing Co. Liquidating Trust, 155 F.3d 644, 658 (3rd Cir. 1998)("Under Fed.R.Civ.P. 9(b), plaintiffs must plead with particularly the circumstances of the alleged fraud. They need not, however, plead the date, place or time of the fraud, so long as they use an alternative means of injection precision and some measure of substantiation into their allegations of fraud." (internal citations omitted).

Further, it is crystal clear that in complaints alleging defendant "caused" third parties to submit false claims, the complaint "does not need to obtain actual false claims from those who the defendant caused to present false claims." *see US ex rel. Bergman v. Abbot Laboratories*, 995 F. Supp. 2d 357, 374 (E.D. Pa. 2014), citing *John Underwood v.*

Genetech, 720 F.Supp. 2d 671, 678 (E.D. 2010). Any other holding would eviscerate the FCA "caused to be made" standard because it would create a standard not able to be met by employees of the wrongdoing entities.

This case is on all fours with another case considered in this District back in 2010. *See John Underwood v. Genetech*, 720 F.Supp. 2d 671, 680 (E.D. Pa. 2010). There, as here, defendant argued that the complaint had to be dismissed because Relator failed to plead properly. The Court refused to dismiss, finding "[t]here is no mystery or ambiguity to these allegations. Either Genetech lavishly bribed doctors to prescribe Rituxan for off-label use or it did not. Relator's allegations are sufficient specific both to inform Genentech of the "precise misconduct" charged, and to make it unlikely that Relator has commenced this action in bad faith."

B. *The FAC Satisfies Rule 9(b) and False Claims Act Pleading Jurisprudence.*

When tested against the applicable legal standard, the FAC clear the bar. The FAC alleges the frequency of the kickbacks, stating that Medtronic provided "multiple surgical, interrogation and other staffing kickbacks on a daily basis." FAC ¶ 25. The FAC alleges that the frequency of payment of kickbacks did not vary by location, but rather "[t]his same pattern of providing free services prevailed across the nation, with Medtronic providing multiple surgical, interrogation and other staffing kickbacks on a daily basis." FAC at ¶ 25.

The FAC alleged the time period of Medtronic's fraudulent scheme to pay kickbacks: *see* FAC at ¶ 24 ("To date, Medtronic continues to provide kickbacks in the form of free surgical support, post-implant device interrogation and analysis, and other services.") Importantly, the FAC alleged a precise means to quantify the frequency of

the kickbacks. Namely, the FAC alleges Medtronic scheduled the free services (*i.e*. the kickbacks themselves) on two calendaring programs (Google Calendar and SalesForce); so those records will "demonstrate Medtronic's nationwide and continuous payment of surgical staffing kickbacks." *See* FAC, ¶ 26.

In addition to those FAC allegations, that, standing alone, suffice to satisfy Rule 9(b), the FAC also includes specific examples of Medtronic's payment of kickbacks in Pennsylvania. Relator identified the name of the provider, the date the kickback was provided, and the type of service that Medtronic provided as a kickback. FAC ¶ 25.

The FAC also alleges the scope of the submissions by the Kickback Recipients. *See* FAC at ¶ 25 ("Medtronic's customers (cardiologists and hospitals) billed Medicare, Medicaid, and private insurers to obtain payment for the health care provided to the patients receiving Medtronic devices. Physicians and hospitals receiving staffing kickbacks presented claims for payment to fiscal intermediaries in all fifty states without disclosing the receipt of the staffing kickbacks, and instead falsely certifying that they had complied with the Anti-Kickback laws and regulations.")

Medtronic, forced to acknowledge that the Relator plead date and locations, tries to undercut the specificity of the allegations by resorting to its self-serving circular argument that giving providers free staff is not wrongful conduct. *See* Medtronic Memorandum at 14 (**"**[i]t is not enough to provide the dates and locations of the alleged services when Relator has failed to meet her more fundamental duty of explaining **how** these alleged services were improper in the first place . . . She never alleges how this conduct, assuming it occurred, crossed the line from customer support to felony. The

specificity is illusory; once the surface is scratched the Complaint's deficiencies are still there.") But such argument fails to persuade.

Here, as in the *John Underwood v. Genetech*, 720 F.Supp. 2d 671, 680 (E.D. Pa. 2010) case, there is no mystery or ambiguity. Relator, a former Medtronic employee, alleged Medtronic engaged and continues to engage in a nationwide system of providing kickbacks in the form of free services to providers. Medtronic memorialized this scheme in calendars maintained on Google Calendar and SalesForce. Medtronic is certainly free to prove that it did not engage in this conduct, or that the conduct should be considered lawful customer support for technical products, but the FAC clearly puts Medtronic on notice of the precise misconduct at issue.

IV. THE FAC ALLEGATIONS ABOUT MEDTRONIC'S HIPAA VIOLATIONS ARE RELEVANT.

Medtronic tells the Court that Relator's allegations about HIPAA violations are irrelevant because such violations are not material to the government's decision to pay Medicare or Medicaid claims. Medtronic Memorandum at 17. But the Relator never never plead a separate legal count premised on Medtronic's HIPAA violations. As is crystal clear from a reading of the Relator's complaint, the Relator alleges only one theory of liability: Medtronic engaged in fraud and caused the filing of false claims by providing free staffing to providers. *See* FAC, Count I, which specifically pleads "[h]ad the United States and the Plaintiff States known that Medtronic was paying kickbacks in the form of free surgical staff services, it would not have relied on the false certifications and made payments to the Kickback Recipients."

During the telephone status call with the Court on April 12, 2017 (Dkt. No. 20), Relator's counsel realized that Medtronic counsel was operating under a wrongful

impression that Relator was espousing two different theories of liability, one alleging false claims flowed from Medtronic's remuneration to providers in the form of free staffing and the other alleging false claims based on the regulatory violations of HIPAA. As a professional courtesy, to ensure Medtronic did not incur any unnecessary costs in briefing an opposition to a non-existent claim premised on HIPAA violations, Relator's counsel immediately called Medtronic counsel, and advised that Count I states only a claim based on the free staffing. (This seems quite obvious from the text of the Count I, but Relators' counsel appreciated that Medtronic did not want to risk failing to brief a potential claim.) Relator's counsel also memorialized the phone call in an email to allay Medtronic's concerns.

But the fact that Relator did not plead a Count of liability based on the HIPAA violations as a separate theory of liability does not mean those factual averments are irrelevant to proving that Medtronic knowingly and willfully violated the Anti-Kickback Statute and caused others to file actionable False Claims Act through the free staffing scheme. (And of course, the proper procedure to eliminate irrelevant factual allegations is a motion to strike, not a motion to dismiss.) As explained in the FAC, the HIPAA violations occurred as Medtronic's District Service Managers (such as Relator) and their subordinates used non-secure calendaring systems to track when providers were scheduling cases with Medtronic devices. *See* FAC, ¶ 26. If Medtronic simply sold the providers the devices, and did not provide kickbacks in the form of free staff, Medtronic would have no reason to keep track of all the procedures, and would have no reason to violate HIPAA by calendaring patient names and procedures in a non-secure setting.

Medtronic was so wedded to continuing the nationwide scheme to provide kickbacks to providers that it was willing to run the risk of violating HIPAA and becoming subject to government enforcement efforts. *See* FAC, ¶¶4, 26, 27. The FAC alleges that the HIPAA violations were used to implement the scheme, and the HIPAA violations were disclosed in Medtronic's 10-K for 2013. *See* FAC, ¶¶ 26, 27. Given the importance of 10-K filings, when read in the light most favorable to Relator, (*Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555-556 (2007), *Bistrian v. Levi*, 696 F.3d 352, 365 (3rd Cir. 2012)); these allegations suggest that Medtronic's top executives knew of the ongoing nationwide HIPAA violations, but were unwilling to put the kickback scheme on pause long enough to shift to a HIPAA-compliant scheduling software.

In sum, the allegations should not be stricken or in any way deemed irrelevant to discovery. Evidence regarding Medtronic's HIPAA violations will rebut any Medtronic defenses alleging that the top executives were unaware of the nationwide free staffing scheme. FAC at ¶ 26. And the jury may view the reality that Medtronic was willing to violate HIPAA regulations in their quest to implement the scheme undercut any Medtronic defense that it is law-abiding company that simply failed to appreciate legal complexities inherent in the health care field. In short, Medtronic's effort to deem the HIPAA violations "irrelevant," and thus outside the scope of discovery, should not be countenanced.

V. MEDTRONIC DEVICES ARE NOT EXCLUDED FROM DEFINITION OF DURABLE MEDICAL EQUIPMENT.

Medtronic claims that the Stark law does not apply in any way because implanted defibrillators and cardiac monitors cannot be considered durable medical equipment.

Medtronic reasons that those items "bear no resemblance to the sophisticated implantable devices at issue here." But the regulatory definition does not exclude sophisticated equipment from its reach. 42 C.F.R. 414.202 defines durable medical equipment as equipment that meets the following conditions:

> **(1)** Can withstand repeated use.
>
> **(2)** Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
>
> **(3)** Is primarily and customarily used to serve a medical purpose.
>
> **(4)** Generally is not useful to an individual in the absence of an illness or injury.
>
> **(5)** Is appropriate for use in the home.

As the devices sold by Medtronic appear to meet all these criteria, the Stark law should apply to Medtronic. *See U.S. v. Rogan*, 517 F.3d 449, 452–53 (7th Cir. 2008) (omissions in hospital's Medicare and Medicaid reimbursement claims, which failed to disclose that illegal referrals had occurred or that kickbacks had been paid, were "material" for purposes of government's claims against hospital administrator under False Claims Act (FCA), given that Stark Amendment to Medicare Act barred payment of claims arising from medical services rendered to improperly referred patients); *U.S. ex rel. Pogue v. Diabetes Treatment Centers of America, Inc.*, 238 F.Supp.2d 258 (D.D.C. 2002) (Diabetes treatment center could be liable under False Claims Act, where center caused a claim to be presented by an entity that was covered by the Stark laws, regardless whether the center would be directly liable under the Stark laws). And in any event, even if it does not, that does not provide a compelling reason for the Court to dismiss the entirety of the FAC – with prejudice.

VI. THE FAC ALLEGES A NATIONWIDE SCHEME.

Medtronic argues for the dismissal of all of the Relator's state law counts, claiming "Relator has said nary a specific word about misconduct occurring outside the state of Pennsylvania." Medtronic Memorandum at 18. This is simply false. The FAC provides the Court to a clear roadmap of the nationwide fraudulent scheme.

Specifically, the FAC alleges Medtronic scheduled all of the free services (*i.e*. the kickbacks themselves) on two specific calendaring programs, Google Calendar and SalesForce. *See* FAC, ¶ 26. These calendars capture the date, time, location and name of the physician (as well as the name of the patient). As alleged in the FAC, these records will "demonstrate Medtronic's nationwide and continuous payment of surgical staffing kickbacks." *See* FAC, ¶ 26. The FAC provided a handful of specific examples of the type of information available in the calendars for Pennsylvania (FAC ¶ 25), but this same type of information is available nationwide on the two calendaring systems used by Medtronic to implement the kickback scheme.[5]

The FAC alleged Medtronic's frequency of kickback payments did not vary by location but rather "[t]his same pattern of providing free services prevailed across the nation, with Medtronic providing multiple surgical, interrogation and other staffing kickbacks on a daily basis." FAC at ¶ 25.

[5] Further, as discussed about, the FAC allegations about the HIPAA violations being memorialized (albeit obliquely) in Medtronic's 10-K also provide the Court with allegations supporting an inference that the very highest level of Medtronic was well aware of the free staffing scheme.

VII. CONTROLLING LAW REQUIRES RELATOR TO BE GRANTED LEAVE TO AMEND IF THE COURT IDENTIFIES PLEADING DEFICIENCIES.

Medtronic not only seeks to dismiss the FAC, but argues for a dismissal with prejudice. Medtronic cites to the *Cooper* case, and argues that the "sparsity" of the FAC and the fact that Relator amended it as a matter of right once suffice to support a dismissal with prejudice. At the outset, Medtronic may have found the FAC sparse because, based on citation in its Memorandum, it appears to have read only thirteen of the twenty-eight factual averments. Medtronic fails utterly to contend with the allegations regarding the Google and Salesforce calendar programs, which memorialize with specificity Medtronic's ongoing nationwide scheme to pay kickbacks in the form of free staff. But in any event, Medtronic is asking this Court to ignore Rule 15(a) and controlling jurisprudence that requires that leave to amend be freely granted. *See Foman v. Davis*, 371 U.S. 178, 182 ("If the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claims on the merits.")

Controlling caselaw in this Circuit is on all fours with the present case, and plainly requires that the Court permit Relator an opportunity to amend if the Court is persuaded that the FAC contains pleading defects. *In United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Company*, 839 F.3d 242 (3rd Cir. 2016), this Court held that the district court abused its discretion in dismissing with prejudice rather than permitting Relator an opportunity to amend. There, the district court denied the Relator

any opportunity to amend, but instead dismissed with prejudice, reasoning that any amendment would be futile.[6]

The Third Circuit overturned the dismissal, finding that "we have rarely upheld a dismissal with prejudice of a complaint when the plaintiff has been given no opportunity to amend." *Id.* at 250. This Court noted, "[i]n none of the cases the District Court relied upon did we uphold a dismissal with prejudice where the plaintiff had been given no opportunity to amend its complaint and would not be given an opportunity to amend in the future." *Id*. at 252. The Third Circuit noted that ***"a plaintiff is unlikely to know whether his complaint is actually deficient – and in need of revision – until after the District Court has ruled***." *Id*. at 250 (emphasis added).

The Third Circuit has been quite clear that plaintiffs must be given opportunities to correct pleading deficiencies. For example, in *In Island Green LLC v. Querrard*, 429 Fed.Appx.90 (3rd Cir. 2011), the Court found that the complaint dismissed below was vague and ambiguous: "We cannot determine from the pleading precisely who is alleged to have done what. . . . But what role did each of the Defendants play in "causing" these instruments to be recorded? We are left without a clue." *Id*. at 92.

The Court, however, reversed the dismissal, holding that "the District Court should give Island Green the opportunity to amend its pleadings and re-plead specifically what wrongful conduct was committed and by whom. *See also Bivings v. Wakefield*, 316 Fed.Appx. 177 (3rd Cir. March 11, 2009) (district court erred in not allowing plaintiff an opportunity to amend complaint after a magistrate issued a recommendation of dismissal). There, the Court also held "the policy behind Rule 15 and the principles of

[6] The district court also relied on the "undue delay" factor, which is not at issue here.

Forman require that a timely request to amend by granted, even if that request could have been brought at an earlier dates." *Id*. at 181. *See also New Branch, NAACP v. Town of Harrison, New Jersey*, 907 F.2d 1408, 1417 (3rd Cir. 1990) ("[C]ourts have held that grants for leave to amend complaints should be routinely granted to plaintiffs, even after judgments of dismissal have been entered against them . . .."); *Grayson v. Mayview State Hospital*, 293 F.3d 103, 114 (3rd Cir. 2002).

As the Third Circuit made clear in *Diaz v. Palakovich*, 448 Fed.Appx.211, 216 (3rd Cir. 2011), district courts should not make rulings regarding futility based on the initial complaint, but rather must analyze the complaint as amended. The Third Circuit explained "[f]or a proposed amendment to be futile, the complaint – as amended – must fail to state claim upon which relief could be granted, that is the same standard Federal Rule of Civil Procedure 12(b)(6) contemplates." *Id*. At this procedural stage, Relator, not Medtronic, is the beneficiary of all inferences in its favor. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555-556 (2007). In the event this Court perceives any pleading deficiencies in Relator's FAC, the Court should grant Relator leave to amend.

CONCLUSION

Medtronic's motion to dismiss should be denied. It lacks any legal support for its primary premise that Medtronic's provision of free staff should be deemed legal. The text of the Anti-Kickback Statute as well as caselaw and regulatory materials prove that providing free staff constitutes "remuneration." The FAC alleges Medtronic engaged in a nationwide scheme to provide free staff, and those allegations are entitled to be tested in discovery and trial. The FAC properly alleges a nationwide scheme, and clears the bar on Rule 9(a), as it provides discrete examples of the fraud, as well as a clear roadmap to the documents that will memorialize the entire nationwide scheme (namely Google and

Salesforce calendars). Although the Relator does not believe the FAC suffers from any pleading deficiencies, she stands ready to amend in the event the Court disagrees. But under no circumstances should this Court dismiss this action with prejudice, as doing so likely would be reversible error when measured against the Third Circuit jurisprudence. *See, e.g., In United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Company*, 839 F.3d 242 (3rd Cir. 2016). Relator respectfully requests that the Court deny Medtronic's motion and set dates for the close of discovery, summary judgment motions, and trial.

Respectfully submitted,

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